

## Ethics and Compliance | France | New ethical controls coming for interactions with healthcare professionals

New rules coming into force on 1 October 2020 will give professional associations the power to block contracts or hospitality agreements between Life Sciences Industries and Healthcare Professionals (HCPs).

The rules are being brought in as part of changes to the so-called "Anti-Gift" Law which governs interactions between the Life Sciences Industries and HCPs in France. The Anti-Gift Law has been significantly amended in January 2017 with the introduction of a new ethical control procedure with the HCPs' Professional Associations.

This new control procedure will enter into force as of 1 October 2020 (pursuant to a Decree of June 2020). It applies to contracts (such as investigator, consultant or speaker agreements) and hospitality (invitations of HCPs to medical events where the industry covers registration, travel, meals and hotel accommodation costs).

Under the new regime, contracts and hospitality are still subject to a prior examination by the HCPs' Professional Associations. However, the latter no longer issue non-binding opinions (positive or negative opinions regarding compliance of the contract or hospitality with the rules provided for by the Anti-Gift Law and other ethical principles), beyond certain thresholds, the HCPs' Professional Associations now have the power to authorize (or refuse) the performance of a contract or the implementation of a project for hospitality.

The joint decision (or "Arrêtés") of the Ministry of Health (MoH) and the Ministry of Finance (MoF) determining the thresholds above which the contracts or the hospitality fall in the scope of the new authorisation procedure is dated 7 August 2020 (published at the official journal on 14 August 2020).

Another joint MoH and MoF decision determines the thresholds under which a benefit in kind has a negligible value and can therefore be authorised by exemption to the general prohibition of advantages provided for by the Anti-Gift Law.

### 1. Thresholds for the scope of the new authorisation procedure

Above the thresholds determined by the MoH decision, the new authorisation procedure applies. Below those thresholds, the industry is simply required to notify the draft contract or the hospitality project to the competent HCPs Professional Association for transparency purposes.

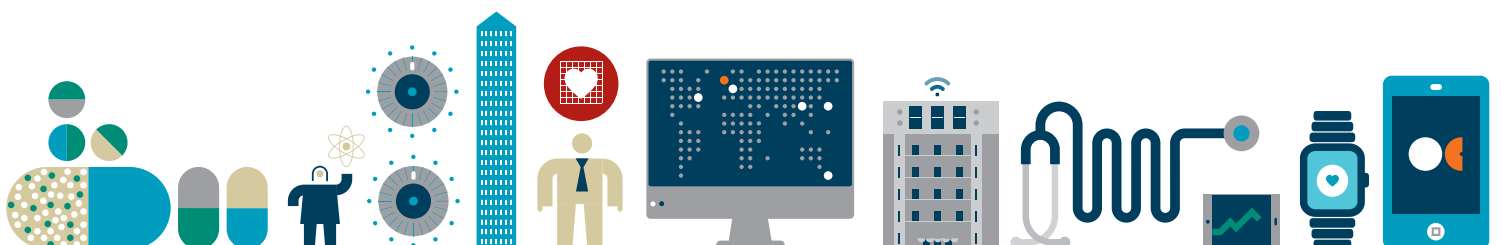
The thresholds (including any applicable taxes) follows:

#### Interactions with HCPs:

- Net remuneration, compensation and expenses for research activities, valuation of research, scientific evaluation, consultancy, provision of services or commercial promotion activities: €200 per hour, up to a maximum of €800 per half-day and in total less than €2,000;
- Grants intended for the exclusive funding of research activities, valuation of research or scientific evaluation: €5,000;

#### Interactions with students:

- Net remuneration, compensation and expenses for research activities, valuation of research, scientific evaluation, consultancy, provision of services or commercial promotion: €80 per hour, within the limit of €320 per half-day and in total less than €800; and
- Grants intended for the exclusive funding of research activities, valuation of research or scientific evaluation: €1,000.



- Hospitality offered during events of professional or scientific nature, or during a product's promotional events: €150 per night, €50 per meal and €15 per snack. The cumulation of those thresholds cannot exceed €2,000, including the cost of transport to the event venue; Registration fees for the events referred to above can be covered in addition to this total amount and must be the subject of a request for authorisation if they exceed €1,000; and
- Funding or participation to the funding of continuing professional education programs: €1,000.

### **Grants to associations of HCPs or Associations of students:**

- Net remuneration, compensation and expenses for research activities, valuation of research, scientific evaluation, consultancy, provision of services or commercial promotion activities: €200 per hour, up to a maximum of €800 per half-day and in total less than €2,000;
- Grants for the exclusive funding of research activities, valuation of research, or scientific evaluation: €8,000;
- Grants for other purpose but linked to health: €1,000; and
- Grants to associations recognized as of a general public interest, including grants for the funding of research activities, research valuation or scientific evaluation: €10,000.

## **2. Thresholds for the determination of advantages of negligible value**

By way of exemption to the general prohibition of advantages, the Anti-Gift Law provides that the industry can provide HCPs with certain advantages if they are of a negligible value.

The joint MoH and the MoF decision determines the thresholds under which some advantages can be authorised as of negligible value.

- Spontaneous (not planned) meals and snacks in the framework of the practice of the HCPs: €30 within the limit of two per calendar year;
- Books or magazines, including subscriptions, pertaining to the practice of the HCPs: €30 per book or magazine and within a total limit, including subscriptions, of €150 per calendar year;
- Product samples: €20 within the limit of three per calendar year. However this limit does not applies to:
  - free samples of pharmaceutical products which are already regulated by the pharmaceutical legislation,
  - demonstration samples intended for the professional education of HCPs if they cannot be used for the care of patients, and
  - demonstration samples used by HCPs for the patients' education or provided to patients for a temporary test.
- Office supplies: €20 in total per calendar year;
- Other products or services pertaining to the practice of the HCPs: €20 in total per calendar year.

## **Key contacts**

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